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| 10/531,822 | 10/24/2005 | Mark Brister | PA1187 | 3938 |

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

| EXAMINER | |
|---|---|
| HOUSTON, ELIZABETH | |
| ART UNIT | PAPER NUMBER |
| 3731 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 01/14/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/531,822 | BRISTER, MARK | |
| | Examiner | Art Unit | |
| | ELIZABETH HOUSTON | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-25* is/are pending in the application.

4a) Of the above claim(s) *1 and 3-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/08 has been entered.

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *112 Sixth Paragraph*

3. It is presumed that applicant is invoking 35 USC 112 sixth paragraph by use of the claim language *"means for applying"* as stated in claim 18. As per the specification, page 9, Para [0036], it is determined that the structure specified as the means for applying is a drive and a sprayer; application systems for dip coating, printing with a roller or a pad, wiping, electrostatic deposition, vapor deposition, expitaxial growth; or equivalents thereof.

4. It is presumed that applicant is invoking 35 USC 112 sixth paragraph by use of the claim language *"means for mixing"* as stated in claim 18. As per the specification, page 9, Para [0036], it is determined that the structure specified as the means for mixing is a mixer or equivalents thereof.

### *Claim Rejections - 35 USC § 102*

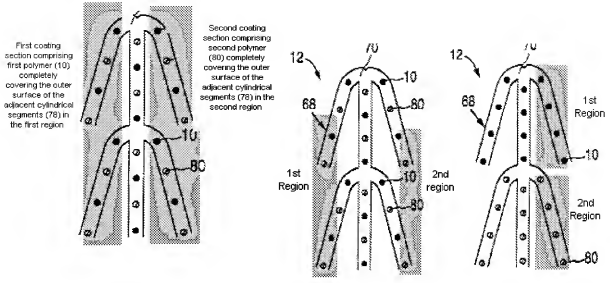
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**6. Claims 1, 3-6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al (US 6,616,765).**

7. Regarding claims 1 and 6, Castro discloses the invention substantially as claimed comprising a catheter, a balloon operably attached to the catheter, and a stent disposed on the balloon (col. 1, lines 19-27). Castro also discloses that the stent has a plurality of stent segments (78, Figs. 11A-12D; Figs. 13F-H) (Note that the depots or cavities are cylindrical and are a segment or portion of the stent.) The stent has a first and second region continuous over at least one pair of adjacent cylindrical segments (see below). A first and second coating sections with first and second polymers (10; 80) are disposed on and completely covering the outer surface of the adjacent cylindrical stent segment (78) in the first and second regions respectively (see below). The first region and second region are discrete, and the first coating section and second coating section are discrete (col. 17, line 60 – col. 18, line 3).




8. Regarding claims 3, 4, 8, and 9, Castro discloses that the first coating section includes a first therapeutic agent and that the second coating section includes a second therapeutic agent (col. 17, line 64 – col. 18, line 2).

9. Regarding claims 5 and 10, Castro discloses that the first and second regions can form a striped or spotted pattern (see above).

### *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**11. Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765).**

12. Regarding claim 22, Castro discloses a stent having a plurality of cylindrical segments (78) having a first discrete region and a second discrete region continuous across at least one pair of the adjacent cylindrical stent segments (see figures above), a first polymer including a first therapeutic agent (10), the first polymer disposed on and completely covering the outer surface of the adjacent cylindrical stent segments (78) in the discrete first region as a first coating section, and a second polymer including a second therapeutic agent (80), the second polymer disposed on and completely covering the outer surface of the adjacent cylindrical stent segments (78) in the discrete second region as a second coating section (see figures above; col. 17, line 60 – col. 18, line 3). Castro does not explicitly disclose that the first region has a longitudinal length greater than the diameter of the stent in an expanded stent. However, it would be obvious to vary the length of the stent and the diameter of the stent to result in a stent where the length is greater than the diameter. It is well known in the art that the length and diameter will need to be varied depending on where the stent is intended to be delivered. Since the region can extend the length of the stent, and the length can be modified to be greater than the diameter of the stent, the modified Castro would meet this limitation.

13. Regarding claim 23, Castro further discloses that the first and second discrete regions are separated by a bare section (see above).

14. Regarding claims 24 and 25, Castro discloses the invention substantially as claimed above except for exact dimensions. However, as shown in the figures above, the location of the first and second regions and thus the dimensions of the bare section are variable. Additionally, the dimension of the bare section will change depending on whether the stent is expanded or compressed. Thus, it would have been obvious to vary the locations of the regions to meet the limitations of the claim.

15. Regarding claims 11 and 18, Castro discloses the invention substantially as claimed above, further disclosing mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (col. 11, lines 7-13), applying the first polymer solution to the first region to form a first coating section completely covering the outer surface of the adjacent cylindrical stent segments in the first region (col. 14, lines 65-67), mixing a second polymer and second therapeutic agent with a solvent to form a second polymer solution (col. 17, line 62 – col. 18, line 4), and applying the second polymer solution to the second region to form a second coating section completely covering the outer surface of the adjacent cylindrical stent segments in the second region (col. 18, lines 14-32). Castro does not explicitly disclose that the first region has a longitudinal length greater than the diameter of the stent in an expanded stent. However, it would be obvious to vary the length of the stent and the diameter of the stent to result in a stent where the length is greater than the diameter. It is well known in the art that the length and diameter will need to be varied depending on where the stent is intended to be delivered. Since the region can extend the length of the stent, and the

length can be modified to be greater than the diameter of the stent, the modified Castro would meet this limitation.

16. Castro fails to specifically disclose that the solvent mixed with the second polymer and second therapeutic agent is a second solvent, but teaches that it could be a second solvent (col. 11, lines 55-59; col. 12, lines 20-24). Choosing a solvent based on the polymer chosen implies that if a second polymer is used, then a second solvent will also be used. Further, Castro discloses that all other variables of the second composition are different than that of the first, so it would have been obvious to choose a second solvent when forming the second polymer solution.

17. Regarding claims 12 and 19, Castro further discloses the first and second polymer solutions may be applied simultaneously (col. 17, lines 61-64).

18. Regarding claims 13 and 20, Castro discloses curing the first and second polymer solutions (col. 9, lines 64-65).

19. Regarding claims 14 and 21, Castro further discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (col. 6, lines 24-35).

20. Regarding claims 15-17, Castro further discloses mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).

***Response to Arguments***

21. Applicants remarks submitted 09/29/08 were addressed in the advisory action mailed on 10/22/08. No new arguments have been provided.

***Conclusion***

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731